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National Vaccine Advisory Committee

HPV Working Group Proposed Recommendations for NVAC Consideration

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National Vaccine Advisory Committee – HPV Working Group Proposed Recommendations for NVAC Consideration

Introduction and Background

There are an average of 25,900 newly diagnosed cases per year of human papillomavirus (HPV)-associated cancer in the United States[1,2]. An estimated 14 million people are newly infected with HPV each year and nearly half of these infections occur in people between the ages of 14-25 years[3]. While most infections resolve over time, persistent infection with oncogenic HPV types is associated with a variety of cancers. Virtually all cervical cancers are due to HPV along with 90 percent of anal, 69 percent of vaginal, 60 percent of oropharyngeal, 51 percent of vulvar, and 40 percent of penile cancers[1]. Further, 87 percent of anal, 76 percent of cervical, 60 percent of oropharyngeal, 55 percent of vaginal, 44 percent of vulva and 29 percent of penile cancers are caused by oncogenic HPV types 16 or 18[4]. Of the 35,000 HPV cancers reported in 2009 in the U.S., 39 percent occurred in males[1].

Currently there are three HPV vaccines available in the United States, which target and have been clinically proven to prevent infection by HPV types 16 and 18, the two types responsible for the most HPV-associated cancers. The bivalent vaccine (HPV2) is designed to protect against types 16 and 18. A quadrivalent vaccine (HPV4) protects against HPV types 16 and 18 as well as two additional types (6 and 11) that are the most common causes of genital warts. The nonavalent vaccine (HPV9) prevents persistent infection from HPV types 6, 11, 16 and 18 and an additional five oncogenic HPV types (types 31, 33, 45, 52 and 58), therefore offering expanded protection against additional HPV cancers. To prevent cancers associated with HPV infections, the Advisory Committee on Immunization Practices (ACIP) recommends HPV immunization for all children aged 11 or 12 with the licensed three-doses series[2]. The ACIP has recommended routine HPV immunization for girls since 2006 and extended the recommendation to include boys in 2011.

Despite the ability of HPV vaccine to protect against oncogenic infections and the associated cancers, in 2013, rates for initiation of the HPV vaccine series are 57.3 percent for girls and 34.6 percent for boys and completion of the HPV vaccine series remain below 40 percent for girls and 15 percent for boys.[2] These completion rates are well below the national *Healthy People 2020* target of 80 percent. These rates also highlight challenges, some similar and some unique, to both initiating the first HPV vaccine dose and completing the three dose series.

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Charge to the National Vaccine Advisory Committee

To address the currently low HPV vaccination coverage rates, the Assistant Secretary for Health (ASH) charged the National Vaccine Advisory Committee (NVAC) to review the current state of HPV immunization, to understand the root cause(s) for the observed relatively low vaccine uptake (both initiation and series completion), and to identify existing best practices all with a goal of providing recommendations on how to increase use of this vaccine in young adolescents.

NVAC established the Human Papillomavirus (HPV) Working Group (Working Group) in February 2013. Table 1 shows the Working Group membership. In July 2013 the Working Group began hearing from external experts and stakeholders to inform the group's work and recommendations. The schedule of invited speakers appears in Table 2.

Concurrently, the President's Cancer Panel (PCP), a federal advisory committee of the National Institutes of Health's National Cancer Institute charged with monitoring the development and execution of the activities of the National Cancer Program was working on its annual report to the President. The PCP highlighted opportunities for primary prevention of cancer and focused on the use of HPV vaccines to prevent HPV-cancers. Its report, Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer, was released on February 10, 2014 and provided recommendations on how to increase HPV vaccination use (Appendix A).

The PCP presented its recommendations to NVAC on February 11, 2014. Among its recommendations, the PCP suggested NVAC, "be given responsibility for monitoring the status of uptake and implementation of the recommendations." NVAC asked the Working Group to fully review the report and determine whether NVAC should endorse and adopt the recommendations of the PCP and advise the ASH to do the same. Following the review of the report by the Working Group, the following five recommendations were provided for the consideration of the full NVAC:

Support for the PCP Report and Recommendations

1. **The ASH should endorse the PCP report, Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer, and adopt the recommendations outlined therein (PCP recommendations can be seen in Appendix A).**

2. **As the PCP recommended, NVAC should, monitor "the status of uptake and implementation of the recommendations." This should be done by hearing an annual progress report from HPV vaccination stakeholders identified in the PCP report.**

Additional Proposed Recommendations to NVAC

NVAC further asked the Working Group to determine whether the report completely addressed the charge given from the ASH or if NVAC should consider making additional recommendations. The Working Group identified three additional recommendations that complement those found in the PCP report. These recommendations were developed after hearing from several external experts in the field and incorporating the most recent data on strategies to increase HPV vaccination coverage. The ASH also asked NVAC to identify strategies to overcome barriers to both initiation and completion of the HPV vaccine series. While many strategies identified are relevant for both, some strategies are most applicable to either initiation or completion of the vaccine series and are described in the following proposed recommendations by the Working Group to NVAC.

3. **The ASH should work with relevant agencies and stakeholders to develop evidence-based, effective, coordinated communication strategies to increase the strength and consistency of clinician recommendations for HPV vaccination to adolescents (both males and females) in the recommended age groups and to improve acceptance among parents/guardians, adolescents and young adults.**

   Recommended communication strategies include the following:

   a. **Develop practical tools to increase clinicians' skills and confidence in promoting HPV vaccination as a routine adolescent vaccine and part of routine adolescent care. These communication tools should equip clinicians to emphasize HPV vaccine as a cancer prevention strategy, to increase clinicians' ability to respond to questions from parents/guardians and adolescents about HPV as a sexually transmitted infection, and to enable clinicians to effectively address parental hesitancy.**
   b. **Develop evidence-based, culturally competent communication strategies for parents/guardians, adolescents and young adults that address key beliefs driving decisions to vaccinate and address barriers to vaccination.**

c. **Promote collaboration among all stakeholders to coordinate communications and messaging that increase message consistency across professional organizations and their constituencies.**
d. **Utilize multiple methods for communication including one-on-one counseling, public health messaging, social media, and decision support systems.**
e. **Promote science-based media coverage about HPV vaccination and appropriate response to media coverage that does not adequately reflect the science of HPV vaccines and HPV vaccination recommendations.**

Both the PCP and Working Group concluded that weak and inconsistent provider recommendations along with low parental demand for HPV vaccination are two significant barriers to increasing coverage rates. National Immunization Survey data show that elimination of missed clinical opportunities to administer HPV vaccination would result in coverage rates between 80 and 90 percent for the first dose. Missed clinical opportunities are defined as visits to a provider where at least one of the other recommended adolescent vaccinations was received[2]. These data are concerning as they indicate that adolescents are both visiting their providers and receiving routine vaccines, but are not being vaccinated against HPV. These data also indicate a great opportunity for improving in HPV vaccination coverage. The recommendation above builds upon several found in the PCP report to develop strategies to support providers in effectively communicating the importance of HPV vaccination, to build parent and adolescent demand for HPV vaccination, and to coordinate stakeholders to encourage consistent evidence-based messaging.

Providers most often cite financial concerns along with parental attitudes and concerns as barriers to providing HPV vaccination to their patients[5]. In addition, discomfort with addressing questions about sexually transmitted infections and safety concerns are also barriers for providers[6,7]. Office strategies, such as reminder recall systems, and the distribution of information and educational materials from provider professional organizations may help increase vaccination rates.

The National Immunization Survey reported that one-third of parents/guardians of girls and more than half of parents/guardians of boys did not receive a recommendation for HPV vaccination from their clinicians[2]. While providers anticipate parental hesitation for HPV vaccination as described above, most parents/guardians report they would accept the vaccine for their adolescent children if their providers recommended it. Surveys of parents/guardians who have refused HPV vaccination for their children give a broad range of reasons, including needing more information about HPV

vaccination. In addition, parents/guardians also cite perceived safety concerns, concerns about the vaccine's potential effect on sexual behavior, low perceived risk of infection, or that their children are too young to need this vaccine as reasons for delaying or refusing HPV vaccination for their children[5].

Therefore, the Working Group suggests the need to consider strategies that target the key issues described above such as increasing knowledge and addressing parental and provider concerns. The Working Group recommends supporting providers with the information and tools they need to effectively and confidently recommend HPV vaccination for their patients and engaging in any conversations that arise from that recommendation. The Working Group further recommends development of targeted communication strategies for parents/guardians and adolescents.

Finally, the Working Group suggests the need for improved collaboration between diverse stakeholders to increase the consistency and coordination of messages to promote HPV vaccination. A broad community of stakeholders is dedicated to increasing HPV immunization. This is a vaccine with the potential to reduce morbidity and mortality of HPV cancers. With over 25,000 cancer cases each year in the U.S., this potential is significant. Building on the shared support of the cancer and sexually transmitted infection prevention, adolescent health and immunization communities will go a long way to increasing public confidence in this vaccination.

4. **NVAC recommends the ASH should work with the relevant agencies and stakeholders to strengthen the immunization system in order to maximize access to and support of adolescent vaccinations, including HPV vaccines.**

   These efforts include the following:

   a. **Addressing barriers to vaccination in venues outside the traditional primary care provider office including pharmacies, schools, and public health departments. This may include immunization status assessment and administration of the appropriate doses towards completion of the HPV vaccination series.**
      i. **Develop strategies to overcome barriers regarding reimbursement for vaccination administration and compensation of vaccine administrators and their staff.**
      ii. **Strengthen Immunization Information Systems (IIS) to allow pharmacies, school-located programs, and public health clinics to view and query**

patient immunization records and submit records of immunizations administered to their state IIS which ensures proper communication and record of immunization histories are available to the patient's primary care provider, vaccination administrator, and the state public health system.

iii. **Encourage collaboration and sharing of best practices for successful vaccination programs at pharmacies, schools, and public health clinics.**

b. **Working with relevant agencies and stakeholders to increase the widespread use of quality improvement strategies, such as Assessment, Feedback, Incentives, and eXchange (AFIX) visits, to support and evaluate HPV immunization practices within all vaccination venues.**

c. **Encouraging widespread adoption of state centralized reminder recall for adolescent vaccines and reporting of vaccinations into existing immunization information systems and electronic health records.**

In 2008, NVAC issued a report and paper on adolescent vaccinations that outlined strategies to create a system for adolescent immunization[8]. This report highlighted that fewer adolescents access the medical system for preventive care, either in public or private delivery venues and that, when they do, it is most often for acute care. Therefore, ensuring adolescents have access to vaccines and other preventive care measures faces unique challenges. The topics addressed in the 2008 report with unique applications to adolescent immunization were alternative venues for vaccine administration, financing, consent for immunizations, communication, surveillance, and the potential for school entry requirements[8]. Much progress has been made towards addressing the recommendations outlined in the 2008 report. Notably, the Affordable Care Act ensures reimbursement for all ACIP-recommended adolescent vaccinations at in-network providers. In addition, national coverage targets have been established along with systems of surveillance of adolescent vaccine coverage, disease burden and vaccine safety. However, some of the same challenges identified still exist. In the recommendation above, the Working Group once again turns attention to the immunization system and recommends ways to continue to increase access to immunization services for adolescents and utilize proven methods to increase coverage. The strategies outlined in this recommendation are especially important to addressing barriers related to completing the three dose HPV vaccine series.

As identified in the 2008 report and also highlighted in the PCP report, using appropriate complementary settings for adolescent vaccination is an important strategy for reaching adolescents and ensuring their access to vaccination services. The physician office or medical home is an essential venue for health care delivery, including immunizations, and does provide vaccines to a large portion of adolescents. However, given adolescents' healthcare utilization patterns, this venue alone may not adequately provide access for all adolescents, especially for HPV vaccination, which requires follow up visits to complete the three dose series. The Working Group, therefore, believes other venues must be considered to reach national immunization goals and assure maximum protection of adolescents. Towards this goal, the Working Group recommends addressing barriers to vaccination at pharmacies, schools, and public health clinics.

While many physician professional organizations prefer all vaccinations be given within the medical home, there is growing recognition that additional consideration and new strategies may be required for HPV vaccination given the unique challenge of the three dose series along with the low vaccination coverage rates. The American Academy of Family Physicians (AAFP) provided a letter to the chairs of the Working Group outlining their position regarding HPV vaccines given outside the medical home (Appendix B). In this letter, the AAFP states that it would accept the second and third HPV vaccine doses be administered outside the medical home as long as those sites were required to report all doses given to the medical home and state registry.

Despite growing support for alternative venues for vaccination, many challenges remain which prevent scaling them up nationally. The PCP concluded pharmacies were the most promising alternative setting at this time and so made recommendations to overcome barriers specific to pharmacy based vaccination. The Working Group supports those recommendations. In addition, after much discussion, the Working Group concluded that while the challenges to school-located vaccination programs may be great, their potential to increase access and ultimately vaccination coverage rates was worth continued effort and attention.

One of the primary barriers to vaccination programs at pharmacies, schools, and public health clinics is reimbursement and compensation. While the Affordable Care Act requires first dollar coverage for ACIP-recommended vaccines, including HPV vaccine, alternative settings are not always considered in-network providers and therefore are ineligible for reimbursement for vaccines administered. Therefore creating in-network status for alternative vaccination sites will be required to make these programs feasible[9]. Even with in-network status, billing insurance is a

challenge within the school setting as students are covered by public or an array of private insurers. Further, compensation for staff time and administration costs are often not adequately covered by insurance. The Working Group recommends the development of strategies to overcome these barriers.

A second challenge to alternative settings is their ability to adequately document vaccine doses to state IIS and to the adolescents' primary care providers[9,10]. Providers in alternative settings often do not have access to state immunization information systems or medical records. In addition, there are not standardized methods for alternative settings to submit vaccines administered to their state registries or report back to primary care providers. Therefore, the Working Group recommends addressing these issues of access to immunization information systems and medical records to ensure proper documentation and facilitate partnerships with primary care providers.

There are additional challenges, unique to school-located vaccination programs that the Working Group discussed. For example, the principal of each school ultimately decides whether or not to allow vaccination programs to run at their schools. Acquiring consent forms from students and their parents/guardians is also a large challenge. To overcome these barriers, the Working Group recommends collaboration and sharing of information amongst pharmacies, school-located programs, and public health clinics. Vaccination in alternative venues is happening successfully in some locations. They have found ways to overcome the barriers identified above in addition to other challenges specific to the setting. Ensuring their best practices and methods for success are shared widely will help expand these programs to additional locations and expand access to vaccination services for adolescents as certain alternative venues may work in some settings better than others.

Finally, the Working Group recommends widespread use of quality improvement strategies and state or regionally centralized reminder recall systems. These programs have been shown to successfully increase vaccination coverage rates and therefore should be adopted more broadly[11].

5. **The ASH should encourage the review or development of available data that could lead to a simplified HPV vaccination schedule. In addition to a review that could impact existing vaccines, manufacturers of HPV vaccines in development should also consider opportunities to support the simplest HPV immunization schedule while maintaining vaccine effectiveness, safety, and long-term protection.**

Growing research suggests equivalent protection from HPV disease may be possible with fewer vaccine doses[12–15]. A simplification of the schedule, by reducing the number of doses required or vaccinating at alternative ages, would help to relieve some of the difficulty in series completion and reduce cost. Immunological non-inferiority has been shown for two doses in 9-13 year olds compared to three doses in 15-25 year olds[12,14,15]. In addition, early data from a trial in Costa Rica for the HPV2 also suggest equivalent efficacy of one and two doses[13]. These data have led to the European Medical Agency and the World Health Organization to recommend a two-dose schedule, and many countries have adopted a two-dose schedule. However, while the data look promising, further post-licensure data are needed to confirm fewer doses are equally effective at preventing persistent HPV infection and provide long-lasting protection. Antibody levels to HPV vaccine have been demonstrated for up to five years post vaccination[16,17]. Further research is planned to determine duration of protection and antibody levels through at least 14 years post series completion. Therefore, the Working Group suggests that NVAC recommend that the ASH encourage continued review of available data or support for additional data that could concretely answer whether fewer doses are equivalent in both effectiveness and safety to the current three-dose schedule and if alternative ages of administration are a viable option based on long term protection. The Working Group notes that any changes to the schedule are the responsibility of ACIP and is aware that ACIP continues to review these data.

Given the potential changes outlined above, the Working Group had lengthy discussions on how best to communicate a change in vaccine recommendation, dose schedule, or both. The Working Group cautions that attention should be paid to ensuring the public and vaccine providers understand the reasons for and data supporting any changes made. In addition, the Working Group stressed that providers should continue to recommend and provide HPV vaccination during this period of potential transition.

Conclusion

With more than 25,000 cases of HPV-cancer diagnosed annually in the U.S., routine administration of HPV vaccines is imperative. HPV vaccination of the 11-12 year old population could reduce the rates of persistent HPV infection which is currently the leading cause of cervical, anal, oropharyngeal, vaginal, vulvar, and penile cancers[1]. The low rates of vaccination highlight the many challenges to both initiating the first HPV vaccine dose and ensuring the three-dose series is completed. Following the recommendations made by the Working Group and the PCP can ease

these challenges. The Working Group recommends that NVAC review HPV vaccination coverage data at least annually to assess the impact of both the PCP and Working Group recommendations to assess the strategies that are being developed to respond to them and, ultimately, their impact on HPV vaccination coverage.

References

1. Jemal A, Simard EP, Dorell C, et al. Annual Report to the Nation on the Status of Cancer, 1975-2009, Featuring the Burden and Trends in Human Papillomavirus (HPV)-Associated Cancers and HPV Vaccination Coverage Levels. *J Natl Cancer Inst*. 2013;105(3):175-201. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3565628&tool=pmcentrez&rendertype=abstract. Accessed March 4, 2013.

2. Stokley S, Jeyarajah J, Yankey D, et al. Human papillomavirus vaccination coverage among adolescents, 2007-2013, and postlicensure vaccine safety monitoring, 2006-2014--United States. *MMWR Morb Mortal Wkly Rep*. 2014;63(29):620-624. http://www.ncbi.nlm.nih.gov/pubmed/25055185. Accessed November 11, 2014.

3. Satterwhite CL, Torrone E, Meites E, et al. Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2008. *Sex Transm Dis*. 2013;40(3):187-193. doi:10.1097/OLQ.0b013e318286bb53.

4. Gillison ML, Chaturvedi AK, Lowy DR. HPV prophylactic vaccines and the potential prevention of noncervical cancers in both men and women. *Cancer*. 2008;113(10 Suppl):3036-3046. http://www.ncbi.nlm.nih.gov/pubmed/18980286. Accessed November 12, 2014.

5. Holman DM, Benard V, Roland KB, Watson M, Liddon N, Stokley S. Barriers to human papillomavirus vaccination among US adolescents: a systematic review of the literature. *JAMA Pediatr*. 2014;168(1):76-82. http://www.ncbi.nlm.nih.gov/pubmed/24276343. Accessed November 5, 2014.

6. Vadaparampil ST, Malo TL, Kahn JA, et al. Physicians' human papillomavirus vaccine recommendations, 2009 and 2011. *Am J Prev Med*. 2014;46(1):80-84. http://www.ncbi.nlm.nih.gov/pubmed/24355675. Accessed November 6, 2014.

7. Kahn JA, Cooper HP, Vadaparampil ST, et al. Human papillomavirus vaccine recommendations and agreement with mandated human papillomavirus vaccination for 11-to-12-year-old girls: a statewide survey of Texas physicians. *Cancer Epidemiol Biomarkers Prev*. 2009;18(8):2325-2332. http://www.ncbi.nlm.nih.gov/pubmed/19661092. Accessed November 11, 2014.

8. The promise and challenge of adolescent immunization. *Am J Prev Med*. 2008;35(2):152-157. http://www.ncbi.nlm.nih.gov/pubmed/18617084. Accessed November 12, 2014.

9. Shah PD, Gilkey MB, Pepper JK, Gottlieb SL, Brewer NT. Promising alternative settings for HPV vaccination of US adolescents. 2014. http://informahealthcare.com.ezproxyhhs.nihlibrary.nih.gov/doi/full/10.1586/14760584.2013.871204. Accessed November 12, 2014.

10. Lindley MC, Boyer-Chu L, Fishbein DB, et al. The role of schools in strengthening delivery of new adolescent vaccinations. *Pediatrics*. 2008;121 Suppl :S46-S54. http://www.ncbi.nlm.nih.gov/pubmed/18174320. Accessed November 12, 2014.

11. Recommendations regarding interventions to improve vaccination coverage in children, adolescents, and adults. Task Force on Community Preventive Services. *Am J Prev Med*. 2000;18(1 Suppl):92-96. http://www.ncbi.nlm.nih.gov/pubmed/10806981. Accessed November 12, 2014.

12. Dobson SRM, McNeil S, Dionne M, et al. Immunogenicity of 2 doses of HPV vaccine in younger adolescents vs 3 doses in young women: a randomized clinical trial. *JAMA*. 2013;309(17):1793-1802. http://www.ncbi.nlm.nih.gov/pubmed/23632723. Accessed November 11, 2014.

13. Kreimer AR, Rodriguez AC, Hildesheim A, et al. Proof-of-principle evaluation of the efficacy of fewer than three doses of a bivalent HPV16/18 vaccine. *J Natl Cancer Inst*. 2011;103(19):1444-1451. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3186781&tool=pmcentrez&rendertype=abstract. Accessed November 11, 2014.

14. Romanowski B, Schwarz TF, Ferguson LM, et al. Immune response to the HPV-16/18 AS04-adjuvanted vaccine administered as a 2-dose or 3-dose schedule up to 4 years after vaccination: results from a randomized study. *Hum Vaccin Immunother*. 2014;10(5):1155-1165. http://www.ncbi.nlm.nih.gov/pubmed/24576907. Accessed November 11, 2014.

15. Lazcano-Ponce E, Stanley M, Muñoz N, et al. Overcoming barriers to HPV vaccination: non-inferiority of antibody response to human papillomavirus 16/18 vaccine in adolescents vaccinated with a two-dose vs. a three-dose schedule at 21 months. *Vaccine*. 2014;32(6):725-732. http://www.ncbi.nlm.nih.gov/pubmed/24355090. Accessed November 11, 2014.

16. Harper DM, Franco EL, Wheeler CM, et al. Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial. *Lancet*. 2006;367(9518):1247-1255. doi:10.1016/S0140-6736(06)68439-0.

17. Villa LL, Costa RLR, Petta CA, et al. High sustained efficacy of a prophylactic quadrivalent human papillomavirus types 6/11/16/18 L1 virus-like particle vaccine through 5 years of follow-up. *Br J Cancer*. 2006;95(11):1459-1466. doi:10.1038/sj.bjc.6603469.

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Table 1

NVAC HPV Working Group Members

Member	Organization
Sarah Despres	NVAC WG Chair
Wayne Rawlins	NVAC WG Chair
Walt Orenstein	NVAC Chair
Philip Hosbach	NVAC
Vish Viswanath	NVAC
Mitch Rothholtz	NVAC
Richard Beigi	NVAC
Jamie Loehr	AAFP
Rodney Willoughby	AAP
Linda Eckert	ACOG
Debbie Saslow	ACS
James Turner	American College Health Association
Kim Martin	ASTHO
Melinda Wharton	CDC
Rebecca Gold	CDC
Julie Morita	Chicago Department of Public Health
Mary Beth Hance	CMS/CMCS
Nancy Lee	HHS Office of Women's Health
Valerie Borden	HHS Office of Women's Health
Litjen Tan	Immunization Action Coalition
Maureen Hess	FDA
Paul Etkind	NACCHO
Nichole Bobo	National Association of School Nurses
Bob Coyle	NCI
Carolyn Deal	NIH
Douglas Lowy	NIH/NCI
Noel Brewer	President's Cancer Panel
Jessica Kahn	Society of Adolescent Health and Medicine
David Salisbury	UK Department of Health
Bruce Gellin	NVPO
Sharon Bergquist	NVPO
Maggie Zettle	NVPO
Karin Bok	NVPO
Katy Seib	NVPO

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Table 2

NVAC HPV Working Group Schedule of Invited Speakers

Topic	Speaker
Current epidemiology of vaccination coverage and VPD/background and proposed solution strategies	
CDC - MMWR July report	Melinda Wharton and Shannon Stokley
International perspective (UK and Canada)	David Salisbury and John Spika
Industry perspective	Merck - Liana Clark
Research - communication	Dan Kahan
Provider barriers and federal opportunities	
Provider Groups	Elizabeth Sobczyk and Jamie Loehr
President's Cancer Panel Follow up from PCP report	Barbara Rimer
Systems barriers and federal opportunities	
Utilizing pharmacies: What remains to be done with state legislation and registries	Mitch Rothholtz
Alternative Locations/programs - schools (Chicago)	Ken Alexander and Rachel Caskey
AFIX	Noel Brewer and Shannon Stokley
Parental and adolescent barriers and federal opportunities	
Communicating with parents and teens	Jessica Kahn
Adolescent Health community strategies	Wilma Robinson
Opportunities to engage cancer organizations and other interested stakeholders	Nichole Bobo
Potential changes to vaccine products and dosing	
Alternative schedules/New vaccine development	Doug Lowy
Draft recommendation – discussion on the need for additional recommendations	

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Appendix A

President's Cancer Panel Recommendations and Responsible Stakeholders

Goals and Objectives	Responsible Stakeholder(s) and Other Entities
Goal 1: Reduce Missed Clinical Opportunities to Recommend and Administer HPV Vaccines	
Objective 1.1: CDC should develop, test, disseminate, and evaluate the impact of integrated, comprehensive communication strategies for physicians and other relevant health professionals.	Centers for Disease Control and Prevention
Objective 1.2: Providers should strongly encourage HPV vaccination of age-eligible males and females whenever other vaccines are administered.	Healthcare providers Health professionals organizations (e.g., American Academy of Pediatrics, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, Society for Adolescent Health and Medicine)
Objective 1.3: Healthcare organizations and practices should use electronic office systems, including electronic health records (EHRs) and immunization information systems (IIS), to avoid missed opportunities for HPV vaccination.	Centers for Disease Control and Prevention Health professionals organizations (e.g., American Academy of Pediatrics, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, Society for Adolescent Health and Medicine)
Objective 1.4: Healthcare payers should reimburse providers adequately for HPV vaccines and for vaccine administration and services.	Health insurance companies America's Health Insurance Plans Medicaid Healthcare organizations
Objective 1.5: The current Healthcare Effectiveness Data and Information Set (HEDIS) quality measure for HPV vaccination of adolescent females should be expanded to include males.	National Committee for Quality Assurance

Goals and Objectives	Responsible Stakeholder(s) and Other Entities
Objective 1.6: Create a *Healthy People 2020* HPV vaccination goal for males.	U.S. Department of Health and Human Services
Goal 2: Increase Parents', Caregivers', and Adolescents' Acceptance of HPV Vaccines	
Objective 2.1: CDC should develop, test, and collaborate with partner organizations to deploy integrated, comprehensive communication strategies directed at parents and other caregivers, and also at adolescents.	Centers for Disease Control and Prevention
Goal 3: Maximize Access to HPV Vaccination Services	
Objective 3.1: Promote and facilitate HPV vaccination in venues outside the medical home.	State and local health departments State legislatures American Pharmacists Association
Objective 3.2: States should enact laws and implement policies that allow pharmacists to administer vaccines to adolescents, including younger adolescents.	State legislatures Health professionals organizations (e.g., American Academy of Pediatrics, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, Society for Adolescent Health and Medicine) American Pharmacists Association
Objective 3.3: Overcome remaining barriers to paying for HPV vaccines, including payment for vaccines provided outside the medical home and by out-of-network or nonphysician providers.	Health insurance companies, health insurance exchanges America's Health Insurance Plans State insurance commissions
Goal 4: Promote Global HPV Vaccine Uptake	
Objective 4.1: The United States should continue its collaboration with and support of GAVI to facilitate HPV vaccine introduction and uptake in low-income countries.	The President Congress U.S. Department of Health and Human Services • Centers for Disease Control and Prevention • National Cancer Institute • U.S. Agency for International Development

Goals and Objectives	Responsible Stakeholder(s) and Other Entities
Objective 4.2: The United States should continue to support global efforts to develop comprehensive cancer control plans and cancer registries in low- and middle-income countries.	The President Congress U.S. Department of Health and Human Services • Centers for Disease Control and Prevention • National Cancer Institute
High-Priority Research to Advance Prevention of HPV-Associated Cancers	
	U.S. Department of Health and Human Services • Centers for Disease Control and Prevention • National Institutes of Health Pharmaceutical and biotechnology companies Other public and private funders of biomedical research

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Appendix B

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

July 23, 2014

US. Department of Health & Human Services
National Vaccine Advisory Committee (NVAC)
Attention: Working Group Chairs, Sarah Despres and Wayne Rawlins
200 Independence Avenue S.W. Washington, D.C. 20201

Dear Ms. Despres and Mr. Rawlins:

This letter is intended to communicate the American Academy of Family Physicians' position regarding Human Papillomavirus (HPV) vaccines given outside the medical home. The AAFP's current policy regarding vaccines given outside the medical home reads as follows: "The AAFP strongly recommends that patients receive all immunizations recommended by the AAFP in their medical home. When recommended vaccines are provided outside of the medical home all pertinent vaccine related information should be provided to the patient's medical home."

The AAFP has a strong preference that all vaccines be administered to patients in the context of the medical home. In particular, the AAFP feels that the first vaccine in the HPV series should be given in the medical home so that the clinician can review the benefits, potential side effects, and schedule of the HPV vaccine series with the patient and/or the family.

However, recognizing the poor uptake of the HPV vaccine in the United States, if the subsequent doses of the series were given at an alternative location such as a pharmacy or vaccine clinic, the AAFP would find that option acceptable AS LONG AS the clinician at the location is REQUIRED to report the dose to the medical home as well as to the state vaccine registry if applicable.

Your work with immunizations is an important contribution to increasing awareness and we wish you the best in this endeavor.

Sincerely,

Jeffrey J. Cain, MD, FMFP
MFP Board Chair